

Guidance and Procedures Number: 12

Title: IRB Review Process – Communication of IRB Actions

Date of Last Revision: February 26, 2009

I. Introduction

The IRB communicates concerns and suggestions regarding human subject protection issues to investigators following each step of its review. In accordance with federal regulations, IRB communications regarding the approval, disapproval or modifications required to secure IRB approval of research activities are in the form of written correspondence.¹

IRB staff are responsible for drafting IRB communications regarding proposed research and any modifications required by the IRB as a condition for IRB approval of proposed research.

All IRB communications are reviewed and approved by the IRB Chair and/or designated IRB member prior to dissemination to the Investigator.

II. Possible IRB Actions

A. The convened Board may vote on one of the following determinations:

- Approval
- Accepted Pending Modification, contingent upon the Chair's or his/her designee's acceptance of requested modifications
- Accepted Pending Modification, contingent upon the primary reviewers' acceptance of requested modifications
- Deferral
- Consultant Review
- Tabled
- Disapproval
- Not Human Subjects Research
- Not Engaged in Human Subjects Research

B. An IRB Chair/designee conducting a review under Expedited procedures may make one of the following determinations:

- Approval
- Accepted Pending Modification, contingent upon the reviewer's acceptance of requested modifications
- Referred for Full Committee Review
- Not Human Subjects Research
- Not Engaged in Human Subjects Research

¹ 45 CFR 46.109(d) and 21 CFR 56.109(e)

III. Approval Notices and Approval Periods

- A. IRB staff will issue the approval notice to document the IRB's approval decision, including any restrictions or conditions of the research, which will be documented as a "codicil" on the approval notice.
- B. Unless otherwise indicated, the approval period for research requiring full committee review will end one year from the date of the meeting, and the approval period for research reviewed under expedited review procedures will end one year from the date of the IRB Chair/designee's review.

IRB approvals are valid until 11:59 p.m. on the expiration date listed on the approval notice. Investigators are therefore allowed to conduct research activities on the expiration date listed on their approval notices.

- C. Approval of modifications to previously approved research will not change the previously assigned expiration date.

IV. Accepted Pending Modification, contingent upon the Chair's or his/her designee's acceptance of requested modifications

- A. IRB staff will notify the investigator of the Board's concerns in writing. The Chair or his/her designee will review and approve the correspondence prior to investigator notification.
- B. Upon receipt of the investigator's response, IRB staff will prepare an evaluation of the response to include any regulatory or administrative guidance for the Chair/designee.
- C. The reviewer will review the investigator's response.
- D. This process may be replicated until the Chair/designee finds that the submission is ready for approval. At this time, IRB staff will issue an approval notice.
- E. Alternatively, the Chair/designee may determine that the response requires the review of another member or full Committee review. In this case, the response will be forwarded to the designated members and/or full Committee.

V. Accepted Pending Modification, contingent upon the primary reviewers' acceptance of requested modifications

- A. IRB staff will notify the investigator of the Board's concerns in writing. The Chair or his/her designee will review and approve the correspondence prior to investigator notification.
- B. Upon receipt of the investigator's response, IRB staff will prepare an evaluation of the response to include any regulatory or administrative guidance for the primary reviewers. In order to facilitate the completion of the review process, the delivery of the response and written evaluation to the primary reviewers will not be dependent upon the distribution of materials for review at the next convened Board meeting.

- C. Reviewers will review the investigator's response and will submit their written comments to OPRS within 3-5 business days.
- D. This process may be replicated until the reviewers find that the submission is ready for approval. At this time, staff will issue an approval notice.
- E. Alternatively, the reviewers may make following determinations:
 - 1. The response requires full Committee review. In this case, the response will be forwarded to the full Committee; *OR*
 - 2. Accepted pending modification, contingent upon the Chair's or his/her designee's acceptance of requested modifications.

VI. Deferral

- A. IRB staff will notify the investigator of the Board's concerns in writing. The Chair or his/her designee will review and approve the correspondence prior to investigator notification.
- B. Upon receipt of the investigator's response, staff will prepare an evaluation of the response to include any regulatory or administrative guidance for the Board. IRB staff will prepare the response for full Committee review.
- C. IRB staff will schedule the investigator for attendance at the meeting, if applicable.
- D. The Board will review the response and may vote on any of the possible determinations listed in Section II(A).

VII. Consultant Review

Investigators may not be informed when "internal" consultant review (i.e., individuals who serve as an IRB member on one of the other UCLA IRBs not reviewing the given study) is requested. When "external" consultant review is requested, IRB staff and/or the IRB Chair/designee will notify the investigator of the request for consultant review, and provide the investigator an opportunity to identify individuals, if any, s/he does not wish to review the protocol.

VIII. Tabled

- A. A submission may be tabled due to one or more of the following reasons:
 - 1. Lack of appropriate expertise in attendance;
 - 2. Lack of sufficient information to conduct an adequate review; or
 - 3. Lack of time/loss of quorum.

- B. IRB staff will notify the investigator of the Board's action in writing, and will apprise the Investigator of the meeting date for which the submission has been re-scheduled for review.

IX. Disapproval

- A. IRB staff will notify the investigator of the Board's concerns in writing. The Chair or his/her designee will review and approve the correspondence prior to investigator notification.
- B. Upon receipt of the investigator's response, staff will prepare an evaluation of the response to include any regulatory or administrative guidance for the Board. IRB staff will prepare the response for review by the convened Board.
- C. IRB staff will schedule the investigator for attendance at the meeting, if applicable.
- D. The Board will review the response and may vote on any of the possible determinations listed in Section II.A.

X. Not Human Subjects Research

- A. Both the convened IRB and the IRB Chair/designee reviewing under an Expedited procedure may decide that a protocol does not meet the definition of "research" and/or does not involve "human subjects" and therefore does not require UCLA IRB review and approval or Certification of Exemption from IRB review.
- B. The investigator will be notified of the IRB determination in writing.

XI. Not Engaged in Human Subjects Research

- A. Both the convened IRB and the IRB Chair/designee reviewing under an Expedited procedure may decide that UCLA is not "engaged" in a human subjects research protocol, and that therefore neither UCLA IRB review nor approval or Certification of Exemption from IRB review is required.
- B. The investigator will be notified of the IRB determination in writing.

XII. Referred for Full Committee Review

- A. The IRB Chair/designee reviewing under an Expedited procedure may decide that a request for additional information should be sent to the investigator prior to the Full Committee review. If such a decision is made, the following steps will be involved.
 - 1. Such correspondence will be prepared by IRB staff for review and approval by the reviewer prior to dissemination.
 - 2. Upon receipt of the investigator's response, staff will include the correspondence and response along with the submission materials and any applicable regulatory or administrative guidance and checklists for the IRB.

3. The Board will review the submission, including the response, and may vote on any of the possible determinations listed in Section II(A).

XIII. Communication of IRB Actions to Institutional Offices and Officials

- A. Principal Investigators are responsible for notifying institutional officials and offices of IRB findings and actions as may be required according to the specifics of the proposed research.
- B. Where IRB findings and actions are routinely relevant to an institutional office or official, OPRS and the relevant office or official shall agree upon an appropriate method of notification.

OPRS currently makes available an online version of its database, refreshed nightly, by which offices such as the Office of Contract and Grant Administration may obtain information about relevant IRB findings and actions.²

- C. For particular situations in which notification of institutional offices or officials is warranted (such as non-compliance), OPRS shall copy relevant offices and officials on resultant correspondence.
- D. The Vice Chancellor for Research may request copies of relevant documentation, such as correspondence and meeting minutes, as needed for investigations, quality assurance or other purposes.
- E. The Vice Chancellor for Research is provided copies of the IRB minutes on a monthly basis.

Regulations:

21 CFR 56.109
45 CFR 46.109

References:

OHRP Guidance on Written IRB Procedures, January 15, 2007.
<http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd107.pdf>

² <http://webapps.oprs.ucla.edu/>